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10-17-02

Docket No. 59154-A/JPW/GJG

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Virginia W. Cornish

Serial No. : 09/768,479 Examiner: K. Kerr

Filed : January 24, 2001 Art Unit: 1652

For : AN IN VIVO SCREEN USING CHEMICAL INDUCERS OF
DIMERIZATION

1185 Avenue of the Americas
New York, New York 10036
October 7, 2002

Assistant Commissioner for Patents
Washington, D.C. 20231

SIR:

RESPONSE TO SEPTEMBER 5, 2002 RESTRICTION REQUIREMENT

This is a Response to the Restriction Requirement issued September 5, 2002 in connection with the above-identified application. A response to the September 5, 2002 Restriction Requirement was due October 5, 2002. However, since October 5, 2002 falls on a Saturday, the next succeeding day which is not a Saturday, Sunday or Federal holiday, i.e. Monday, October 5, 2002, is considered timely under 37 C.F.R. §1.7 and this Response is being timely filed.

Claims 91-133 are pending in the subject application.

In the September 5, 2002 Restriction Requirement, the Examiner required restriction to one of the following allegedly distinct invention as follows:

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- I. Claims 91-125, drawn to compounds, complexes thereof and cells containing the complexes;
- II. Claims 128-132, drawn to methods of dimerizing fusion proteins in a cell; and
- III. Claim 133, drawn to methods of identifying molecules that bind a known target.

The Examiner alleged that the inventions are distinct, each from the other, because they are related as product and process of use. The Examiner stated that the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that, referring to M.P.E.P. §806.05(h). In the instant case the Examiner alleged that the compounds can be used for a materially different purpose, such as in drug treatment therapies.

The Examiner also alleged that the inventions of groups II and III are distinct because these methods use different reagents, and utilize distinct steps, to produce different products

On the assertion that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, the Examiner alleged that restriction for examination purposes as indicated is proper.

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The Examiner also alleged that the subject application contains claims directed to patentably distinct species of the invention, namely the compounds of claims 96 and 106-110, and that if applicant elects Groups I or Group II, applicant is required to elect a single disclosed species for initial prosecution on the merits.

In response, applicant hereby elects, with traverse, Group I, claims 91-127. Within this group applicant elects for initial prosecution the species of claim 107, also with traverse.

Initially, applicant points out that although the Examiner identified group I as containing claims 91-125, applicant believes this to be a typographical error and claims 91-127 is what the Examiner intended because claim 126 and 127 are also directed to cells, which the Examiner included in group I.

Restriction

Applicant traverses the restriction requirement at least because all of the process of use claims of Group II, as identified by the Examiner, depend on and incorporate the limitations of product claim 91 of elected Group I. While applicants note the Examiner's reliance on M.P.E.P. § 806.05(h) to restrict the product from the use, applicants respectfully point out that the relied upon section does not address how to treat such claims once the product claim is allowed. M.P.E.P. § 806.05(i) addresses how to treat such claims once the product claim is allowed:

Where the product claims are allowable (i.e., novel and nonobvious), restriction may be required only

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where the process of making and the product made are distinct (MPEP § 806.05(f)); otherwise, the process of using must be joined with the process of making and product made, even if a showing of distinctness can be made between the product and process of using (MPEP § 806.05(h)). (Emphasis added)

Indeed, such treatment of the claims is rational in view of the minimal burden on the Examiner to examine process of use claims which incorporate all of the limitations of allowed product claims. While applicants contend that the restriction between Groups I and II is not proper for reasons which follow, applicants hereby respectfully request that the Examiner, at minimum, examine the use claims of Group II once the product claims of Group I are found allowable.

Applicants, however, respectfully request that the Examiner reconsider and withdraw the restriction requirement in its entirety. Under 35 U.S.C. § 121, restriction may be required if two or more independent and distinct inventions are claimed in one application. Under M.P.E.P. § 803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden.

The inventions of Groups I, II, and III are not independent. Under M.P.E.P. § 802.01, "independent" means there is no disclosed relationship between the subjects disclosed. The invention of Group I is drawn to compounds and which can be used in the invention of Groups II and III. Applicants therefore maintain that the Groups are not independent and restriction is not proper.

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Furthermore, under M.P.E.P. § 803, the Examiner must examine the application on the merits if examination can be made without serious burden, even if the application would include claims to distinct or independent inventions. That is, there are two criteria for a proper requirement for restriction: 1) the invention must be independent and distinct, **and** 2) there must be a serious burden on the Examiner if restriction is not required.

Applicant respectfully submit that there would not be a serious burden on the Examiner if restriction is not required, because a search of the prior art relevant to Group I would necessarily turn up the prior art relevant to the claims of Groups II and III, and *vice versa*, because any such search would certainly uncover uses of the compounds of Group I. Since there is no burden on the Examiner to examine Groups I-IV together in the subject application, the Examiner must examine the entire application on the merits.

In view of the foregoing, applicants maintain that restriction is not proper under 35 U.S.C. § 121 and respectfully requests that the Examiner reconsider and withdraw the requirement for restriction. At minimum, applicant respectfully requests that Group II should be examined with elected Group I in the subject application.

Election of Species

Applicant traverses the election of species requirement under M.P.E.P. § 803. Under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. Applicant

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contends that there would not be a serious burden on the Examiner if election were not required.

All of the recited species of applicant's claimed invention contain a methotrexate moiety as part of a dimeric molecule. A search of the prior art for any dimeric molecule containing methotrexate would reveal prior art relevant to applicant's species. Such a search is not believed to pose an undue burden. Since the search and examination of the application can be made without serious burden, applicants respectfully request that the Examiner withdraw the election requirement.

Notwithstanding the foregoing, should the examination of the subject application begin with the elected species and the elected species be found allowable, applicants respectfully request examination of the generic claims pursuant to 37 C.F.R. § 1.146 and M.P.E.P. § 809.02, *et seq.*

No fee is deemed necessary in connection with the filing of this Response. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

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Date